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Keywords Aspiration thrombectomy · Acute limb ischemia · Closure device · Vascular complication

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Introduction

Acute leg ischemia, a manifestation of peripheral arterial disease, carries a high risk of amputation and mortality. For the treatment and the prevention of its sequelae, emergent percutaneous or surgical revascularization is used. For acute leg ischemia, percutaneous techniques are sufficient to resolve the occlusion in most of the cases and in particular elderly patients benefit from nonsurgical alternatives [1–3].

Percutaneous aspiration thrombectomy (PAT) has been a proven and effective technique since it was first described by Sniderman in 1984 [1–3]. Adjunctive use of catheter-directed local thrombolysis or mechanical clot fragmentation with angioplasty balloons may be adopted to facilitate the aspiration therapy. The technique of PAT requires the use of large access site end-hole catheters and a syringe to aspirate clots from vessels. The main limitation of the aspiration technique often involves the size and burden of the clot. To facilitate the procedure, larger aspiration catheters and consequently larger introduction sheaths, which are inherently associated with more access site

complications, are desirable [1–3]. To control bleeding complications, a quick and reliable closure of the large access site is mandatory. The "preclose" technique, an off-label use of a suture-mediated vessel closure device (VCD; ProGlide®) described for percutaneous endovascular aortic repair, may fulfill these specific needs of PAT [4].

The purpose of this study was to analyze retrospectively the clinical outcomes of using a suture-mediated VCD for antegrade closure of large access sites in a sample of patients with acute limb-threatening ischemia undergoing PAT.

Materials and Methods

Study Design

This study was conducted according to the standards of the declaration of Helsinki. Due to the retrospective nature of this study, the local ethical committee waived institutional review board approval. All patients gave written consent for the clinically indicated thrombectomy procedures. The interventionists performing the procedures had more than 4 years of experience in this particular field.

A single-center registry was constructed to assess the clinical outcomes of a suture-mediated closure system (ProGlide® 6F, Abbott Vascular, Redwood City, CA) in patients undergoing PAT. The device was approved by the FDA in 1997 for retrograde closure of arterial access sites up to 8 F [5]. The ProGlide consists of a monofilament suture deployed with an automated, pre-tied knot to close the femoral artery by arterial wall approximation. We adopted the known "preclose" modification of its standard application for antegrade closure of the common and proximal superficial femoral artery.

Intervention

After local anesthesia, the same 20 G needle was utilized to perform the antegrade puncture of the common femoral or proximal superficial femoral artery and the initial angiogram of the common femoral artery bifurcation in a 30° oblique projection. Depending on the presence of arteriosclerotic disease, the caliber of the artery, and the extension of the arterial occlusion at the puncture site, a second "higher" or more distal puncture was performed. Attention was paid to these anatomical issues, because they may interfere with the introduction of the ProGlide® or respectively, with the pull-back of its anchoring foot. Using Seldinger's technique a 0.018" guidewire (V-18 Control Wire, Boston Scientific Corp., Natick, MA) was introduced and advanced into the superficial femoral artery to exchange the access needle for a 6- or 7-F vascular dilator. Then, a single "preclosure" of the femoral access was performed with a commercially available 6-F suture-mediated closure device (ProGlide®, Abbott Vascular Inc., Redwood City, CA) according to the known technique [6]. The initial introducer size (6–12 F) was chosen based on the diameter of the vessel accessed and the amount of thrombus to be removed. At this stage a bolus of 5,000 IU. of unfractionated heparin was given if the patients were not already on a heparin drip or on therapeutic oral anticoagulation. The clot aspiration was subsequently performed with a 50 cc syringe (to obtain the vacuum) attached to a straight aspiration catheter (6–9 F, Angiomed, subsidiary of CR Bard Inc., Karlsruhe, GE) [7].

If the aspirated clot was repeatedly "lost" as it was pulled through the sheath, the latter was upsized by at least 2 F. We preferred the 11 cm Avanti® introducer (Cordis Corp., Miami Lakes, FL) for this procedure, because it can be clamped easily with a hemostat and because its cap at the hub can be removed easily and reinstalled to facilitate withdrawal of larger clots. If this simple maneuver failed, the thromboembolus was additionally lysed by a course of hand- or injector-driven catheter directed pulse-spray thrombolysis (200,000 IU of urokinase, 5 F multi-slit catheter/Uni*Fuse®, AngioDynamics, Queensbury, NY), followed by mechanical angioplasty balloon fragmentation. Then, aspiration thrombectomy was resumed. Any underlying lesions were treated by balloon angioplasty with or without stenting. In the few instances of acutely thrombosed popliteal aneurysms, stent-grafts were placed first and flow restoration by aspiration thrombectomy was performed thereafter. Finally, the introducer was removed and puncture site hemostasis was achieved by tying the pre-placed ProGlide® suture. To keep the option of an additional ProGlide® placement in case of persisting bleeding, the "safety" guidewire was removed after tying the suture. Activated clotting time measurements were not routinely performed before the accesses were closed.

Inclusion Criteria and Patient Sample

A search of the interventional database of our department revealed 145 interventions with the combined utilization of an aspiration thrombectomy catheter and the aforementioned device from November 2005 to February 2010. After exclusion of retrograde iliac thrombectomies, 119 antegrade interventions were left. To simplify statistical analysis, only the first intervention per patient was counted, resulting in a total of 101 patients. Separation into subgroups for the analysis of the factors contributing to vascular complications at the access site led to 19 patients with and 82 without complications. The patients were referred for emergent percutaneous revascularization either directly from smaller hospitals ($n = 17$, 17 %) or from the

department of vascular surgery ($n = 18$, 18 %) or the angiology clinic ($n = 66$, 65 %) of our center. The angiology clinic conducted the postinterventional examination of all patients according to a standardized clinical follow-up protocol. Within 24 h after the intervention, every patient had follow-up consisting of a physical examination, determination of ankle-arm pressures, and pulse-volume recording. Further examinations followed after 3 and 6 months for the patients from the Department of Vascular Surgery and the angiology clinic. In 77 patients (76 %), an additional duplex ultrasound was performed by a vascular specialist. The ultrasound follow-up is incomplete, because this examination was initially performed on demand and later routinely.

Data Collection

Based on a review of the pertinent literature, a screening chart was created identifying complications and factors that likely contribute to vascular complications. The patient data were gathered from the picture archives and patient information system of the hospital. Emphasis was placed on angiograms and postinterventional documentation, including the first follow-up. According to an internal policy of the interventional team, the operator always took floor notes regarding successful or unsuccessful closure and consequences, such as additional external compression. The scrutinized information was cross-checked with the discharge notes. Special attention was drawn to the cause of deaths and to factors that influenced each complication. Vascular complications were weighted according to the clinical outcome classification of the SIR [8]. Data in Tables 1 and 2 were extracted from the screening chart.

Definitions

Early and late complications were defined separately as occurring within 24 h after the intervention and at 6 months, respectively. The deployment of the device and the closure of the antegrade puncture site were regarded as successful when no additional compression and just a single device were needed.

Everything from persistent mild oozing to serious blood loss was categorized as bleeding. Hematomas were subdivided according to their localization into inguinal and retroperitoneal. Factors with a possible influence on complications are listed in Table 2.

Statistical Analysis

All tests were calculated at a significance level of $\alpha = 0.05$, and confidence intervals were computed at a confidence level of 95 %. Proportions were complemented with a Wilson confidence interval ([9], including continuity correction). Nominal variables were described as frequencies and percentages, whereas the mean $\pm$ standard deviation and ranges were provided for the continuous variables. Tests between groups were performed with SPSS 19 for Windows (SPSS, Chicago, IL). Nominal variables were compared using χ^2 or Fisher's exact tests, depending on the expected frequency in each cell. Continuous variables were compared using the t or Wilcoxon test, depending on a visual check of normality of the underlying measurements. A unifactorial ANOVA was applied when appropriate.

Table 1 Fatalities

	Age (year), gender	Time after intervention	Cause of death	Background and details
1	85, female	1 day	Heart failure	Physicians of the intensive care unit suspected a cardiac reason; PAT was performed because of an embolic arterial occlusion
2	65, male	4 days	Multiorgan dysfunction	Anastomotic bleeding of infected aortobiiliacal graft, postinterventional contralateral iliac vessel occlusion, rhabdomyolysis
3	80, female	4 days	Multiorgan dysfunction	Sepsis in the setting of ischemic colitis, aortic graft of infra renal aneurysm; retroperitoneal hematoma 2 days postintervention
4	75, male	9 days	Multiorgan dysfunction	Aortic bifurcated graft, aortoduodenal fistula
5	58, male	1 month	Heart failure	Terminal heart insufficiency, coronary and valvular heart disease, listed for transplantation
6	93, female	2 months	"Old age"	Information obtained from relatives
7	88, male	5 months	"Old age"	Information from the nursing home
8	77, male	7 months	Cancer	Disseminated bladder cancer
9	62, male	1 year	Not known	At 6 month follow-up, no clinical abnormalities

Table 2 Patient characteristics, adjunctive treatments, and factors possibly associated with vascular complications

Type	Patients ($n = 101$)	p values
Gender	74 (73 %) men	$p1 = 0.54$
	27 (27 %) women	$p2 = 1.00$
Age (year)	Mean 70.1 ± 12.6	$p1 = 0.64$
	Range 18–93	$p2 = 0.64$
BMI (kg/m^2)	Mean 26.5 ± 4.9	$p1 = 0.87$
	Range 19–40	$p2 = 0.31$
Artery/diameter at the access site	21 (21 %) AFS	$p1 = 0.25$
	80 (79 %) AFC	$p2 = 0.49$
Sclerosis	0 = 23 (23 %) 2 = 21 (21 %)	$p1 = 0.046$
	1 = 34 (33 %) 3 = 23 (23 %)	$p2 = 0.77$
Ectasia/aneurysm	6 (6 %)	$p1 = 0.39$
Scarring	1 (1 %)	$p2 = 0.16$ ("anatomical variation")
Etiology/location of occlusion	Thrombotic 70 (69 %); embolic 31 (31 %)	$p1 = 0.76$
	Femoral 23, popliteal 18, crural 10, femoropopliteal 15, popliteo-crural 14, femoropopliteo-crural 21	$p2 = 0.69$ (etiology)
Fluoroscopy time (min)	Mean 29 ± 18.7	$p1 = 0.95$
	Range 2–90	$p2 = 0.2$
Sheath dwell time (min)	Mean 96.4 ± 52.9	$p1 = 0.22$
	Range 13–293	$p2 = 0.46$
Duration of hospital stay (days)	Mean 11.6 ± 17.6	$p1 = 0.13$
	Range 0–115	$p2 = 0.12$
Maximum sheath size (F)	Mean 9.3 ± 1.2	$p1 = 0.55$
	Range 6–12	$p2 = 0.16$
Prior OAC (INR > 1.4)	30 (30 %)	$p1 = 0.47$
		$p2 = 0.5$
Unfractionated heparin	preinterventional bolus 61 (60 %); (2,500–12,500 IU)	$p1 = 0.07$
	i.v. infusion 58 (57 %); (10,000–30,000 IU per 24 h)	$p2 = 0.14$
	None 5 (5 %)	
Anti-aggregation	ASS + clopidogrel 32 (32 %) clopidogrel 3 (3 %)	$p1 = 0.94$
	ASS 45 (44 %) none 21 (21 %)	$p2 = 0.71$
"On-table" urokinase	71 (70 %); (intrathrombic, 50,000–1,000,000 U)	$p1 = 0.7$
		$p2 = 0.49$
PTA (also utilized for clot fragmentation)	66 (65 %)	$p1 = 0.51$
		$p2 = 0.79$
Stent or stent-graft placement	39 (39 %)	$p1 = 0.44$
		$p2 = 0.67$

BMI body mass index, *AFC* common femoral artery, *AFS* superficial femoral artery, *FT* fluoroscopy time, *SDT* sheath dwell time, *OAC* oral anticoagulation, *ASS* acetylsalicylic acid 100 mg, clopidogrel 75 mg, *PTA* percutaneous transluminal arterial angioplasty

0 no calcifications, *I* slight calcifications, *II* moderate calcifications, *III* severe calcifications, *p1* *p* value of the adequate statistical test for association of one factor and the group with and without complications, *p2* *p* value of the adequate statistical test for association of one factor and the subgroups of complications

Results

Successful closure was achieved in 95 patients (94 %; Wilson confidence interval: 87, 98). Device failure was immediately detected clinically and solved in three patients by placement of more than one device (ProGlide®), in two patients by external compression, and in the remaining patient by crossover placement of a stent-graft. Table 2 summarizes the incidence of factors that likely contribute to vascular complications in the whole study cohort.

Closure was always performed by one of four operators with prior experience in retrograde and antegrade closures

using the ProGlide®. All patients underwent suction thrombectomy because of acute or subacute ischemia of the lower extremities. The targeted thrombus could be removed in 83 (82 %) patients with a subsequent sufficient crural run-off. The primary result was only partially successful in 15 (15 %) patients, with failure in 3 (3 %) patients. Dissection ($n = 5$, 5 %) or vessel perforation ($n = 2$, 2 %) was rare and was remote from the access site. In one patient, a femoral-crural bypass was directly accessed and closed with the device four times (4 %) during the course of the data collection period. However, as stated above, just the first intervention was included in the statistical analysis. Lower leg fasciotomy was performed in 14 (14 %) cases and amputation in 6 (6 %) cases; both were necessary due to reperfusion syndrome and irreversible ischemia, respectively, and not caused by the VCD. Salvage bypass surgery was not deemed appropriate for the patients with failed limb revascularization.

Overall, 19 patients (19 %; Wilson confidence interval: 12, 28) had a composite of different vascular complications at the puncture site. None required surgical repair.

In one very obese patient, the VCD failed and subsequent serious bleeding had to be stopped by crossover stent-grafting (Figs. 1, 2), because manual compression of the superficial femoral artery was not considered an option in this particular patient.

In another patient, a retroperitoneal hematoma was confirmed by a CT scan 2 days after the intervention. Blood transfusions had been administered to this patient. The access site was below the inferior epigastric artery on the same side as the hematoma. According to the operator's note, the access closure had been unremarkable. This patient died 2 days later. Taking into account the autopsy findings, sepsis related to the known ischemic colitis followed by multiple-organ failure was assumed to be the primary cause of death (Table 1).

For three minor bleedings or oozing, manual compression was sufficient. Seven patients developed inguinal hematomas. These complications were discovered clinically, and hematomas were verified by ultrasound. None of these patients with hematomas required any specific treatment.

Duplex ultrasound revealed one false aneurysm. At the puncture site, the common femoral artery was ectatic and showed mild calcification. A 10 F sheath had been used for the PAT. Ultrasound-guided compression therapy was successful.

No record of a device-related arteriovenous fistula, infection requiring antibiotics, embolization, nerve injury, or vascular stenosis leading to ischemia was found.

Taking into account only the 84 patients from the angiology clinic and the Department of Vascular Surgery with available post-discharge follow-up visits, no late complications were found.

Among the nine (9 %) cases of death, five occurred within the first month after the intervention. No relationship was observed between death and intervention in the information system (Table 1). However, in the patient with the retroperitoneal hematoma described above, a contribution by the VCD to the death of the patient could not be excluded.

A box plot analysis of continuous factors from Table 2 showed trends toward more deployment complications (Fig. 3). For BMI, fluoroscopy time and sheath dwell time differences appeared only in the subgroup analysis for the type of complication. Regarding hospitalization time and sheath size, differences were already visible in the group containing all complications. Nevertheless, none of the different statistical tests was significant ($p > 0.05$) for any combination of the type of complication or for the overall complication group with any of the factors.

Discussion

This retrospective study examined a suture-mediated VCD for the closure of large arterial access sites after antegrade femoral access in patients undergoing PAT. This setting involves several comorbidities and factors that contribute to access site complications.

Regarding short-term outcomes, the apparently high rate of early complications (19 %) has to be cautioned. Similar procedures have a broad range of hemostatic complication rates for manual compression and VCD [10–13]. Depending on the definitions, the accuracy of follow-up protocols, and diagnostic tools used, complication rates as high as 64 % have been reported [14]. The majority of our patients had duplex-ultrasound in the 24 h follow-up, and for every patient we had floor notes from the operator stating details about the closure. Thus, we uncovered even small and clinically non-relevant hematomas and bleedings. Severe complications that required additional treatment and prolonged hospital stay occurred in only two patients (2 %).

The data most comparable to our setting are those from Duda et al. [15], who used a similar suture-mediated VCD (Perclose Techstar®) in antegrade femoral accesses. Their patients underwent femoropopliteal angioplasties of essentially chronic ischemic limbs. Furthermore, that study included fewer patients, and only a few underwent aspiration thrombectomy, resulting in smaller introducer sheath sizes. The overall early access complication rate in Duda's study was 12.5 % with major complications in 1 %.

Regarding the midterm outcomes, the literature reports that infectious complications usually occur within 2 weeks [16], whereas occlusive changes take place up to 6 months after the intervention [17]. We observed our patients for 6 months after discharge, and neither ischemic nor late infectious complications were reported. This finding is

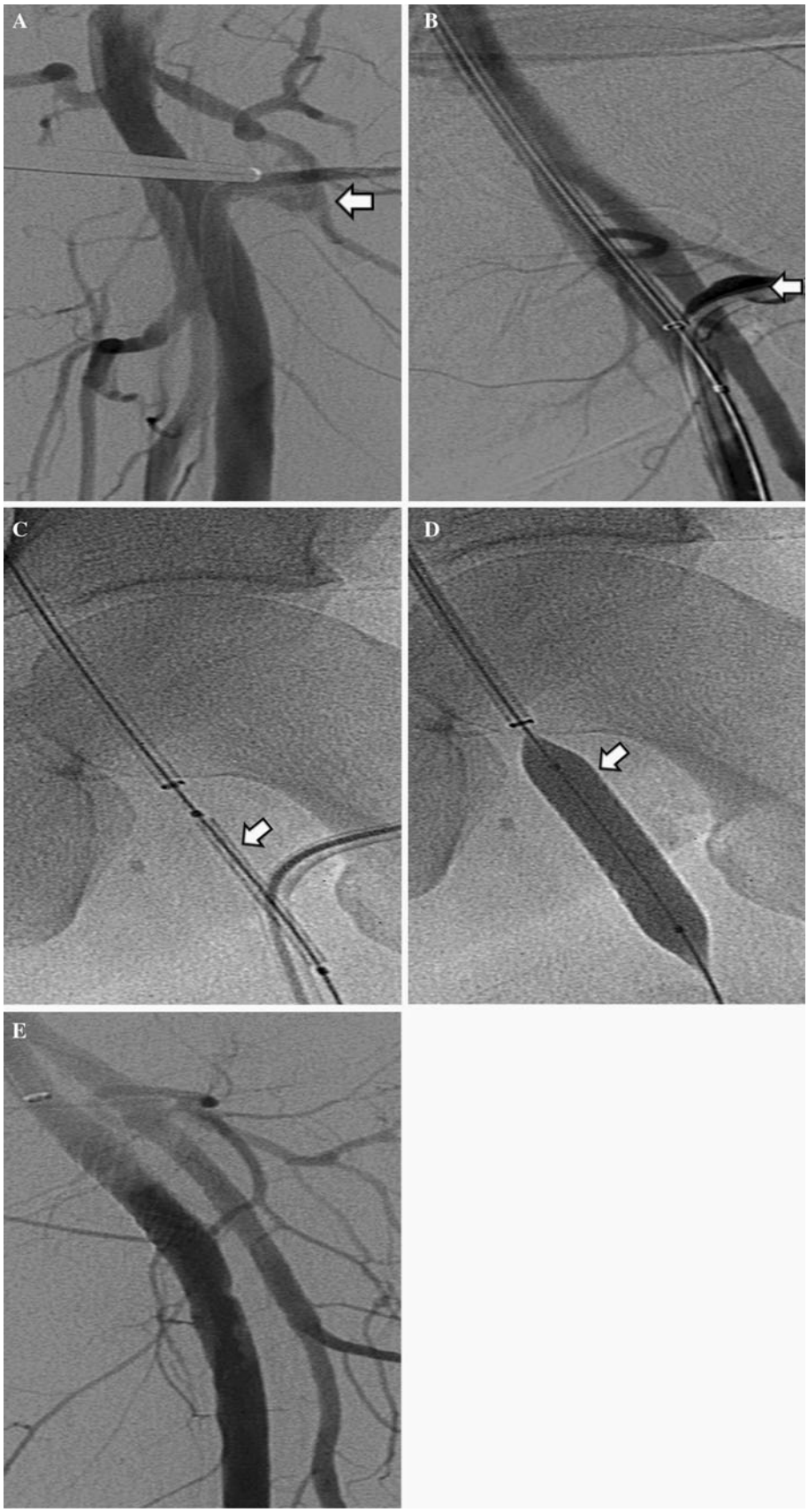

Fig. 1 A 54-year-old morbidly obese male underwent percutaneous treatment of an acutely thrombosed popliteal aneurysm with stent-graft placement, "on-table" thrombolysis, and PAT. We chose to access the superficial femoral artery, because antegrade puncture of the common femoral artery would have resulted in a steep angulation of the device or respectively the introducer sheath. There was serious bleeding at the puncture site after suture-mediated closure. The *white arrows* in (**A**) and (**B**) point to the leakage around the 11 F sheath. The sheath had been re-advanced for hemorrhage control over the "safety wire" after the knot of the Perclose had been tied. Using a crossover technique, stent-graft insertion (Hemobahn 10 × 50 mm; Gore Associates, Flagstaff, AZ) (**C**) and expansion (**D**) were performed to seal the hole. On the completion angiogram (**E**), the superficial femoral artery access was sealed. Surgical treatment was not considered because of its high risk of groin infection in this obese patient

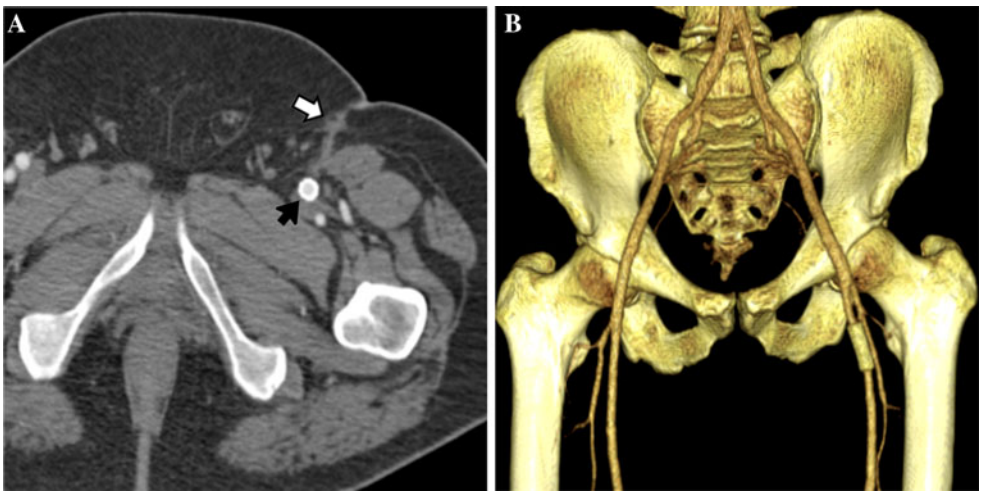

Fig. 2 Follow-up CTA performed at 80 days. The axial image (**A**) depicts the scarring of the long puncture tract in the subcutaneous fat tissue (*white arrow*) as well as the patent stent-graft within the superficial femoral artery (*black arrow*). Volume rendered CTA (**B**), clarifying the anatomy

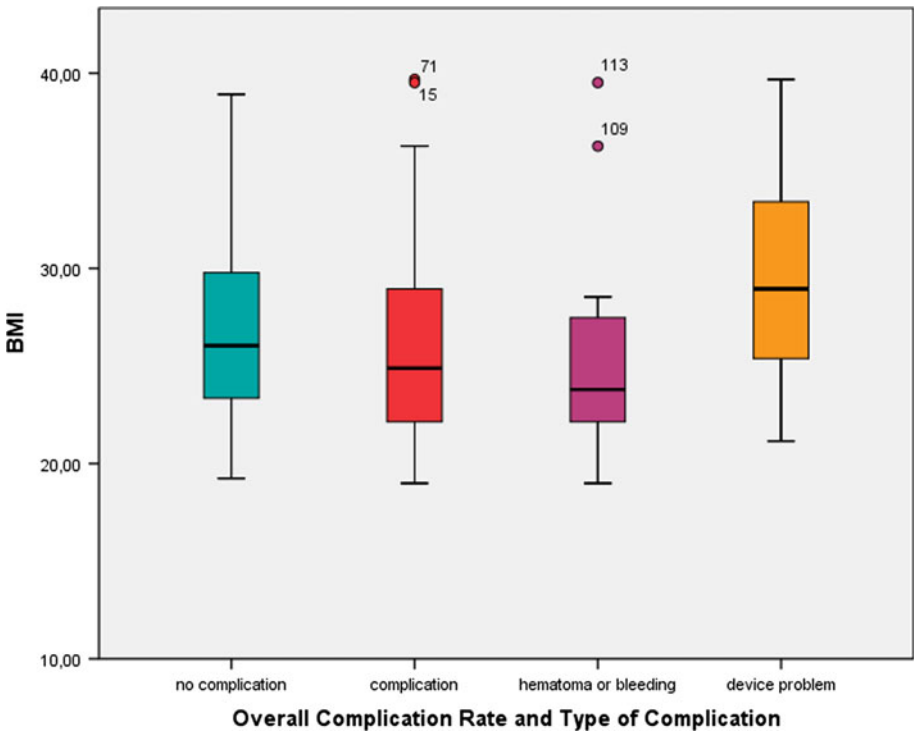

Fig. 3 *Box plots* of an exemplary risk factor on the ordinate (BMI = body mass index in kg/m^2) and its distribution within different subgroups as described on the abscissa. For patients with and without any complications, the *box plots* were similar. After dividing the complications into groups for the type of complication, the subgroup with the device problems showed a higher median; higher and wider IQR (interquartile range) and higher minima and maxima

probably related to the device, which is collagen-free [5]. Thus, the inflammatory response is missing, and collagen cannot be deposed intra-arterially. Additionally, in 2004 the manufacturer improved the trimming mechanism and changed the braided suture to a more inert monofilament [6]. Hence, it was shown in the literature that infections are less likely even though the suture represents a permanent foreign material [18]. For the same reasons, vascular injury with the device resulting in ischemic complication seems to be unlikely [19]. However, cases have been occasionally reported even after 2004 [20]. A device-specific risk is assumed related to the intra-arterial foot of the device, which may cause a dissection of the arterial wall. In our experience, this is not a major concern. However, we made sure that the vessel was not diseased and large enough at the puncture site. Indeed, we did not observe any device-related dissections even after proximal superficial femoral access.

Immediate hemostatic failures were uncommon, and manual compression or a second device was sufficient to achieve hemostasis except in the patient treated with a crossover stent-graft. These results are comparable to published data [6, 10, 15].

The highly selected patient sample (i.e., one type of device, only antegrade insertions, just patients undergoing PAT) may explain why no statistical test could reach a significant difference between the groups with and without complications. Most of the patients had many of the factors summarized in Table 2, regardless of their group affiliation. Our hypothesis is supported by many studies that showed the influence of coexisting factors included in Table 2 on the rate of VCD-related access site complications [21]. Moreover, descriptive box plot analysis revealed trends toward the anticipated direction. Further assessments in this high-risk-group will unlikely supply useful data.

Important limitations of the study relate to its retrospective nature. For instance, in the only fatality, it is difficult to retrospectively analyze to what extent the retroperitoneal hematoma contributed to the death of the patient. The anticoagulation regimen was all but uniform. Immediately before the intervention was started, one third of the patients were receiving warfarin and two thirds of them were on a therapeutic dose of intravenous heparin. Furthermore, 70 % of the patients received nonstandardized amounts of urokinase during the procedure. This spectrum of anticoagulation management is essentially inherent to any revascularization treatment of acute ischemic limbs. Nevertheless, a global anticoagulation assessment (i.e., ACT) at the completion of the intervention would have been useful.

Regarding the late complications, 17 outpatients without a complete 6-month follow-up had to be excluded, which lowered the credibility of our findings regarding midterm outcomes.

Conclusions

This retrospective study showed that by integrating the "preclosure" technique into the time-tested PAT with large catheters, acute lower limb ischemia can be treated successfully at an acceptable rate of ponderable complications at the access site. Additionally, no VCD-related infectious or ischemic complications were discovered at midterm follow-up.

Conflict of interest None.

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